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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/485,071	02/03/2000	NORBERT O. REICH	30794.30USWO	1444

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EXAMINER

LEWIS, PATRICK T

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 04/14/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/485,071	Applicant(s) REICH ET AL.	
	Examiner Patrick T. Lewis	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 31,34 and 36-50 is/are pending in the application.
- 4a) Of the above claim(s) 34,36-45 and 47-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 31 and 46 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 03 February 2000 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of claims relating to GC box pMET, SEQ ID NO: 10 in Paper No. 26 dated August 28, 2003 is acknowledged.
2. Claim 34, 36-45, and 47-50 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 26 dated August 28, 2003. The restriction requirement was made FINAL in the Office Action dated October 29, 2003.

Applicant's Response dated January 28, 2004

3. In the Response filed January 28, 2004, claims 1-30, 32-33, and 35 were canceled. Applicant presented arguments directed to the rejection of claim 31 under 35 U.S.C. 102(b) as being anticipated by Flynn et al. *Biochemistry* (1996), Vol. 35, pages 7308-7315 (Flynn) and the rejection of claim 46 under 35 U.S.C. 103(a) as being unpatentable over Flynn et al. *Biochemistry* (1996), Vol. 35, pages 7308-7315 (Flynn). An action on the merits of claims 31 and 46 is contained herein below.
4. Applicant's arguments with respect to claims 31 and 46 have been considered but are moot in view of the new ground(s) of rejection.

Art Unit: 1623

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

8. Claims 31 and 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Flynn et al. *Biochemistry* (1996), Vol. 35, pages 7308-7315 (Flynn) and Billing-Medel et al. US 6,183,952 (Billing).

Claim 31 is drawn to a synthetic oligonucleotide of at least 26 nucleotides in length comprising a 5mCpG dinucleotide, wherein the 5mC is a C-5 methylcytosine, and which comprises a nucleotide sequence selected from the group consisting of TGACGTCA and SEQ ID NOS: 1-4, 6-12, 14-15, 18-101, 103, 105, 107, and 109, wherein the synthetic oligonucleotide comprises a phosphorothiolate nucleotide. Claim 46 is drawn to a composition comprising a synthetic oligonucleotide of at least 26 nucleotides in length comprising a 5mCpG dinucleotide, and wherein the synthetic oligonucleotide comprises a phosphorothiolate nucleotide, and a pharmaceutically acceptable carrier.

Flynn teaches the deoxyoligonucleotide GC-box b^{met} (page 7309, Table 1).

Flynn differs from the instantly claimed invention in that Flynn teaches phosphoramidite linkages instead of phosphorothiolate linkages as instantly claim and Flynn does not explicitly teach a composition comprising a pharmaceutically acceptable carrier.

Billing teaches that antisense technology can be used to reduce gene expression through triple-helix formation or antisense DNA or RNA, both of which methods are based on binding of a polynucleotide to DNA or RNA (column 26, lines 25-49). Billing further teaches that antisense oligonucleotides act with greater efficacy when modified to contain artificial internucleotide linkages which render the molecule resistant to nucleolytic cleavage. Such artificial internucleotide linkages include methylphosphonate, phosphorothiolate and phosphoroamidate internucleotide linkages.

Claiming an unpatentable compound in combination with a carrier does not render the combination patentable if it would be obvious in the prior art to utilize a carrier with the compound. In the instant case, it would have been obvious to one of ordinary skill in the art at the time of the invention to add a pharmaceutically acceptable with the deoxyoligonucleotide GC-box b^{met} since Flynn teaches that the deoxyoligonucleotide containing CpG dinucleotide were designed to mimic DNA transcriptional cis elements previously reported to have cytosine C-5 methylated regulation (Abstract). DCMTase catalyzes DNA methylation, and DCMTase activity has been linked to tumor development (page 7308, column 2). It would have also been obvious to one of ordinary skill in the art at the time of the invention to employ phosphorothiolate internucleotide linkages in the oligonucleotide of Flynn since Billing teaches that antisense oligonucleotides act with greater efficacy when modified to contain phosphorothiolate internucleotide linkages. The prior art in itself is seen to provide ample motivation for making the instantly claimed invention.

Conclusion

9. Claims 31, 34, and 36-50 are pending. Claims 34, 36-45, and 47-50 are drawn to a nonelected invention. Claims 31 and 46 are rejected. No claims are allowed.


Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patrick T. Lewis whose telephone number is 571-272-0655. The examiner can normally be reached on M-F 10:00 am to 3:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 571-272-0661. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patrick T. Lewis, PhD
Examiner
Art Unit 1623



James O. Wilson
Supervisory Patent Examiner
Technology Center 1600

ptl
April 6, 2004